REMARKS

This amendment is being filed in response to the Office Action dated December 16, 2005 which was issued in response to the Applicant's RCE filed on September 12, 2005. At the time of the Office Action, claims 17-18, 20-41, 45-50, 53, 54, 70, 80-85, and 90 were pending in the instant application, and claims 1-16, 19, 42-45, 51, 52, 55-69, 71-79, and 86-89 were withdrawn. Each of these claims is hereby cancelled without prejudice. New claims 91-122 are presented herein. Consideration of these claims and speedy allowance of the present application is respectfully requested.

The Examiner has objected to the Specification under 35 U.S.C. 132(a), and more specifically to the Amendment filed on June 30, 2003 on the grounds that it introduced new matter into the Specification. The Examiner specifically pointed out as new matter the term "batched product" as inserted throughout the Specification and its definition as inserted on page 8 and continuing on to page 9.

Applicant respectfully submits that the objection under 35 U.S.C. 132(a) is overcome in view of the amendments to the Specification presented herein, which cancel all subject matter deemed to be objectionable by the Examiner. Applicant respectfully submits that entry of new claims 91-122 and the amended Specification overcome all of the issues under 35 U.S.C. 112 and 132(a). Reconsideration of the objection to the specification is respectfully requested.

Notwithstanding the above, for the sake of completeness of the record, it is important to note that Applicant disagrees with the Examiner's assertion that the Amendment filed on June 30, 2003 introduced new matter. This application was filed on July 9, 1999 disclosing and claming a stable isotopic identification and method for

identifying/matching unknown products or samples, with known products or sources, using naturally occurring isotopic concentration data of products, especially in the pharmaceutical industry. In addition, the application discloses and claims an identification and method utilizing isotopic concentration data in a machine readable form for identifying products and tracking products through manufacturing, marketing and use of a product and indexing product information to the product.

Applicant submits, and the record of this case reveals, that a person skilled in the art to which the invention pertains, at the time the present application was filed, would have understood the Specification and the originally filed claims to inherently include the objected-to subject matter. In particular, Applicant respectfully submits that a person skilled in the art upon reading Applicant's Specification, would understand that, for the claimed method to produce a positive indication of identity (i.e., match) between a sample being tested and a known source, the empirical isotopic data corresponding to the source (i.e., the "first empirical data" of claim 91) would need to consistently correlate to the source across the full content of the source. In other words, the source would need to have sufficient homogeneity that analytical data obtained for the source is consistently and accurately attributable to the full content of the source. The skilled artisan would understand that, absent sufficient homogeneity of content and reproducibility of data across the full content of the source, the analytical data obtained for the source would have little or no identifying power. The skilled artisan would have the same understanding with regard to any unknown or sample to be identified when multiple samples are to be taken.

In view of the above, the skilled artisan would have immediately understood that Applicant's identification and method encompass consideration of, and would have specific applicability to "batched products" and "analyzing a batched product for the concentrations of a plurality of naturally occurring stabilize isotopes of said batched product after batching in their anthropogenically isotopically unaltered batched concentrations" as these terms and phrases are widely understood. The skilled artisan would also have immediately understood the concept of "sampling error" to relate to the amount of isotopic concentration variance that can be tolerated within a relatively homogeneous source or within a sample to allow for the inventive method to yield reliable positive identifications. The skilled artisan would likewise have understood that the products identified by the method of the invention would encompass products having (1) a plurality of isotopes, (2) the isotopes being inherently present in the product not of a taggant, (3) the isotopes having stable concentrations over time, and (4) the products being representative and reproducible (i.e., having sampling errors significantly less than the errors of analysis and comparison). Batched products would have been immediately envisaged by a person skilled in the art upon reading the present Specification at the time the application was filed, and the meaning of the term "batched product" would have been understood to include not only compounds or other compositions made using a batch process, but also compounds or other compositions made using other types of processes and subsequently batched by isolating and homogenizing a quantity of the composition prior to isotopic concentration analysis in accordance with the invention.

It is universally known by persons of ordinary skill in the field of pharmaceutical manufacturing that pharmaceutical products are commonly produced using batch processes and thus are "batched products". Examples of such pharmaceutical products are listed on page 3 and elsewhere in the Specification. Throughout the description of a specific embodiment beginning on page 8 of the Specification, the word "product" is utilized to refer to "products" which are well known to persons skilled in the art to be "batched products". It would also be clear to those skilled in the art that the word "product" would also refer to other "batched products" such as explosives, make-up, ammunition, gunpowder, hazardous waste, paper, ink, tires and rubber products, paints and other coatings and other products batched by sampling listed at page 8 of the Specification and in original Claim 8.

A person skilled in the art would also understand from the application that the process of sampling the products to be compared (both the unknown product or sample and the known product or source) is an important step in making positive identifications using the inventive method. Therefore, sampling of both the known (i.e., source) and accomplished using a technique having an error less than the desired error of the comparison in accordance with the method. In order to produce a reliable positive identification using the inventive method, it is important that the sampling of each of the known source and an unknown sample for analysis have an error significantly less than the error of analysis. The application refers to products that would be clearly understood by a person skilled in the art to be representative and reproducible samples of compositions which have been taken from larger samples by sampling techniques having errors significantly less than the error of analysis and the error of comparison

desired by the utilization of the method. Thus it would not be stretching the meaning of the language of the Specification to refer to any of the products spoken about in the application as "batch products" irrespective of whether a batch is made using a batch process or by post-manufacturing batching or sampling, provided that representative and reproducible samples can be obtained by techniques having errors significantly less than the error of analysis and the error desired in the comparison of the method of the invention.

Any person skilled in the pertinent art would also understand from the application that if "batching" of the product either by sampling or by manufacture could not be accomplished, thus resulting in a scenario where representative and reproducible samples could not be obtained by known sampling techniques within an error significantly less than the errors of analysis or the desired errors of comparison, that the method of the invention would merely indicate that there is no reliable identification or match. On the other hand, for all of those products that are successfully and reliably identified by the invention, a person of ordinary skill in the art would recognize that the process would necessarily have included appropriate sampling of a proper batch that is representative, reproducible and homogeneous.

A person skilled in the art would also understand from the application that once batched, error would be introduced into the method of comparison if any batched product subsequent to batching underwent any isotopic concentration altering reactions or other kinetic or thermodynamic alterations of the isotopic concentrations. Such persons would also fully understand from the application that such isotopic concentration altering reactions or other kinetic or thermodynamic processes effecting

isotopic concentrations could occur prior to batching without affecting the method of the invention.

Consideration of new claims 90-122 is respectfully requested. Applicant submits that new claims 90-122 satisfy all requirements of 35 U.S.C. 112 and define subject matter that is novel and nonobvious under 35 U.S.C. 102 and 103 over the art of record, including the previously-cited U.S. patents issued to Welle and Brand et al. whether taken alone or in combination with each other.

For all of the reasons given hereinabove, Applicant respectfully submits that the application is in form for allowance. Applicant respectfully solicits the prompt issuance of a Notice of Allowance.

Respectfully Submitted,

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